UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

OTTO DELCID, LUZ ROMAN, MINA KALLAMNI, MARY MOLINA, CARLO GARCIA, and ANDREA FAHEY, on behalf of themselves and all others similarly situated, Plaintiffs, v. TCP HOT ACQUISITION LLC and IDELLE LABS, LTD., Defendants.	No. 1:21-cv-09569-VSB

MEMORANDUM OF LAW IN SUPPORT OF TCP HOT ACQUISITION LLC AND IDELLE LABS, LTD.'S MOTION TO DISMISS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes, Regulations, and Rules

Administrative Authorities

Other Authorities

Defendants TCP HOT Acquisition LLC ("TCP") and Idelle Labs, Ltd., ("Idelle" and, with TCP, "defendants") respectfully submit this Memorandum of Law in Support of their Motion to Dismiss the Complaint pursuant to Federal Rules of Civil Procedure 9(b), 12(b)(1), and 12(b)(6).

PRELIMINARY STATEMENT

This action challenges defendants' disclosure and manufacturing practices for several aerosol antiperspirants distributed under the Brut and Sure labels (the "Products"). Plaintiffs assert that Products in which any benzene is detected are "adulterated" and "misbranded" under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 9 § 301 *et seq.* ("FDCA"). They also claim that the Products were manufactured in derogation of the Food and Drug Administration's ("FDA") current good manufacturing practices ("CGMP"). Though their claimed harm arises exclusively from alleged violations of the FDCA, plaintiffs do not and cannot assert a claim under federal law. Instead, they assert eleven different common law and statutory claims arising under the laws of California, Florida, and New York. The reason for the omission of an FDCA claim is straightforward: the FDCA does not provide a private right of action. Plaintiffs' claims fail for myriad reasons, but at base each of these failings boils down to the fact that the Complaint asks this Court to create new obligations under state law that are greater than or in addition to the requirements of the FDCA. Only the FDA—not plaintiffs—has the authority to enforce the FDCA.

Five individual plaintiffs allege that they each purchased one can of Brut or Sure, and the remaining plaintiff says she made multiple purchases. Plaintiffs do not say that the Products failed to perform as antiperspirants, although it is not clear that they even could make such an allegation given that plaintiffs do not allege that they actually used the Products. Moreover, plaintiffs do not and almost certainly could not allege that they suffered any adverse health effects from their (limited) use of the Products. Nevertheless, plaintiffs want their money back—a full refund—but that remedy is not available as a matter of law. Absent allegations that they used the Products and

were physically injured by them, plaintiffs lack Article III standing to assert the claims in this action. *See In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Liab. Litig.*, 903 F.3d 278, 287–90 (3d Cir. 2018); *id.* at 290 ("[A]lthough [plaintiff] characterizes her Baby Powder purchases as economic injuries for which she is entitled to relief, she has failed to allege that the economic benefit she received from that powder was *anything* less than the price she paid. In short, she received the benefit of her bargain."). The Complaint and this action should therefore be dismissed pursuant to Fed. R. Civ. P. 12(b)(1).

If standing exists, the Complaint should be dismissed under Fed. R. Civ. 12(b)(6). Plaintiffs' state law claims all rest on the twin allegations that the Products were "misbranded" or "adulterated" under the FDCA, and that they were manufactured in violation of the FDA's CGMPs. Plaintiffs' allegations that defendants violated the FDCA are wrong as a matter of law. The Products were not misbranded or adulterated, nor did defendants violate established CGMPs. *See infra* § II.A–B. But there is more—a lot more. Plaintiffs' state law claims are pre-empted. The Second Circuit and numerous other courts have held that the FDCA broadly pre-empts state law in circumstances analogous to these. Here, plaintiffs' claims are expressly pre-empted because they seek to impose requirements that are different from and in addition to the FDCA. For example, plaintiffs assert the Products were "misbranded" under the FDCA because defendants failed to disclose the presence of benzene. Because the FDCA contains no such requirement, a state law imposing such a requirement is necessarily preempted.

Assuming *arguendo* that plaintiffs have Article III standing and their claims are not preempted, their state law claims should still be dismissed on the merits as a matter of law for multiple, independent reasons. First, plaintiffs' claims for breach of an express warranty fail because, *inter alia*, defendants did not make any warranties about benzene; and plaintiffs' claim

for breach of implied warranty fails because plaintiffs are not in privity with defendants and the Complaint does not allege that the Products failed to work as intended. Second, plaintiffs' statutory fraud claims should be dismissed because the Complaint fails to allege that defendants made any false or misleading representations about the Products. Third, plaintiffs' claim for unjust enrichment fails because, among other reasons, they alleged that their claims are governed by an express agreement. Fourth, plaintiff Fahey's claim for medical monitoring (based on little more than speculation) cannot survive because she failed to plead any facts to support multiple required elements under Florida law.

For all of these reasons, as detailed below, the Complaint (ECF Doc. 21) and this action should be dismissed.

BACKGROUND

A. Plaintiffs' Claims and Allegations

The consolidated Complaint asserts eleven causes of action on behalf of six named plaintiffs. Two of the named plaintiffs assert claims under California law (Molina, Garcia), three under New York law (Delcid, Roman, Kallamni), and one under Florida law (Fahey). With the exception of Ms. Kallamni who does not say when she made her purchase, *see* Compl. ¶ 41, plaintiffs each assert that they recently purchased (in 2020 and 2021) "a canister" of either Brut (Garcia, Delcid, Roman) or Sure (Molina, Kallamni, Fahey), *id.* ¶¶ 39–40, 42–44. While each plaintiff repeats the same rote allegations that they reviewed the "labels and disclosures," the Complaint never says what plaintiffs reviewed or allegedly relied on. *Id.* ¶¶ 39–44.

Beyond these allegations, plaintiffs say little about their purchases. They do not allege that they—as opposed to someone else in their household—ever used the Products. *Id.*[1] And there are

[1] Ms. Molina alleges that she made multiple purchases, Compl. ¶ 42, but she does not allege whether she—as opposed to someone else in her household—used the Sure aerosol products.

certainly no allegations that the Products failed to perform as antiperspirants. Nor do plaintiffs allege that they suffered any adverse health consequences from using "a canister" of one of the Products. *Id*. The Complaint does not nor could it allege that use of a single canister, or even several, would cause any adverse health consequences. Nevertheless, plaintiffs have demanded a refund of the full purchase price of the Products they purchased even though there are no allegations that the Products did not work effectively as antiperspirants. *Id*. ¶¶ 3, 10, 35, 59, 90, 102, 138.

As even plaintiffs concede, the FDA regulates antiperspirants as over-the-counter ("OTC") drugs pursuant to the federal FDCA. In fact, the Complaint repeatedly alleges that defendants violated federal law. *Id*. ¶¶ 3, 14–23, 25–27. Plaintiffs assert that defendants allegedly violated the FDCA because:

- The Products were "mislabeled" because they did not disclose benzene as either an "active" or "inactive" ingredient;
- The Products were "adulterated" because they allegedly contain benzene; and
- The Products were manufactured in violation of CGMPs.

Id. Plaintiffs do not assert any claims under the FDCA, however, because only the FDA can enforce the statute; there is no private right of action. Nevertheless, plaintiffs base each of their eleven state law claims on defendants' alleged violations of the FDCA generally and rules promulgated by the FDA. Indeed, plaintiffs do not allege that the canisters that each plaintiff purchased contained benzene or were within what they claim to be the lots affected with benzene. *See* Compl. ¶ 9.

B. FDA's Pre-Approved Monograph Comprehensively Regulates Drug Labels

As plaintiffs recognize, pursuant to the FDCA, the FDA extensively regulates OTC drugs, including the Products. 21 C.F.R. § 330.5. The FDA makes use of a variety of tools—including proposed orders, enforcement policies, and final rules—to regulate OTC drugs. *See* 21 U.S.C.

§ 393;[2] *United States v. Gel Spice Co.*, 773 F.2d 427, 429 (2d Cir. 1985) (FDCA provides the FDA with various "enforcement mechanisms when it determines that the Act has been violated"); *see also POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 109 (2014) ("[T]he FDCA and its regulations provide the United States with nearly exclusive enforcement authority, including the authority to seek criminal sanctions in some circumstances."); *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 349 & n.4 (2001) (discussing the FDA's "variety of enforcement options" and lack of private right of action under the FDCA).

Most significant among the FDA's tools to regulate OTC drugs is its monograph. *See* 21 C.F.R. § 330.10. The monograph is "a kind of 'recipe book' covering acceptable ingredients, doses, formulations, and labeling." FDA, *Drug Applications for Over-the-Counter (OTC) Drugs* (March 31, 2020).[3] As the Second Circuit explained, the monograph is "a detailed regulation . . . for each therapeutic class of OTC drug products," which "allows manufacturers to bypass individualized review" of individual products they seek to market. *Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 710 F.3d 71, 75 (2d Cir. 2013); *see* 21 C.F.R. § 201.66(c). Through the monograph, the FDA mandates the information, including the active ingredients and inactive ingredients, that must appear on an "outside container or wrapper of the retail package." 21 C.F.R. § 201.66(c). The OTC drug monograph also regulates "the safety, effectiveness, and labeling of all marketing OTC active ingredients." *Id.*

[2] TCP cites and provide links to publicly-available FDA guidance, articles, and regulations throughout this Motion. The Second Circuit holds that such materials are appropriately considered on a motion to dismiss. *See, e.g.*, *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 59–60 (2d Cir. 2016) ("Although this case partially arises on a motion to dismiss, we may properly take judicial notice of [FDA Guidance] . . . because the Guidance is publicly available and its accuracy cannot reasonably be questioned.") (citing Fed. R. Evid. 201(b)).

[3] https://www.fda.gov/drugs/types-applications/drug-applications-over-counter-otc-drugs.

For decades, the FDA has established labeling and testing regulations for antiperspirants. *See*, *e.g.*, 21 C.F.R. Parts 310, 350, 369.[4] Most recently, Congress enacted § 505G of the FDCA through the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"). *See* CARES Act § 3854, Pub. L. No. 116–136, 134 Stat. 281 (2020). The CARES Act deemed final an antiperspirant monograph adopting certain requirements and amendments from prior regulations. *See* FDA, *Over-the-Counter Monograph M019: Antiperspirant Drug Products for Over-the-Counter Human Use* (posted Nov. 23, 2021) (the "2020 Monograph"). The FDA deems an antiperspirant that complies with each condition of the 2020 Monograph to be "recognized as safe and effective and is not misbranded." 2020 Monograph at 1.

C. FDA's "Current Good Manufacturing Practice" Regulations

The FDA has also adopted regulations—Current Good Manufacturing Practice or CGMP—to regulate the manufacture of drugs. 21 C.F.R. pts. 210, 211. The CGMP rules govern all aspects of the manufacturing process, including the design and construction of manufacturing facilities (Subpart C), equipment design and construction (Subpart D), control of components and drug product containers and closures (Subpart E), laboratory controls (Subpart I), and records and reports (Subpart J). *See id.* pt. 211. Layered atop the CGMP regulations are detailed FDA guidance documents. *E.g.*, U.S. Dept. of Health and Human Services: FDA, *Analytical Procedures and Methods Validation for Drugs and Biologics: Guidance for Industry* (July 2015), https://bit.ly/33V0ZKk. FDA personnel with "specialized technical expertise" handle "inspections, investigations and training operations." FDA, *Technical Assistance*, https://bit.ly/31LkfaG (last updated May 1, 2015).

[4] For example, in 1990, FDA issued a final rule establishing that certain active ingredients found in antiperspirants are unsafe and render the products misbranded. 55 Fed. Reg. 46914. In 2003, FDA issued a final antiperspirant monograph, which became effective in 2004. 68 Fed. Reg. 34273. FDA further amended its guidelines for effectiveness testing of antiperspirants in 2011 (76 Fed. Reg. 31470) and again in 2014 (79 Fed. Reg. 68115).

The FDA has several options to ensure compliance with the CGMP rules. The primary tool is facility inspections, through which the FDA "ensure[s] that establishments consistently manufacture [quality] drug products," assesses "conformance to CGMP requirements for [FDA] decisions," and seeks "to improve . . . compliance with regulations." FDA, *Compliance Program – Program No. 7356.002*, at 5 (Oct. 31, 2017), https://bit.ly/3ahPn5x. If an inspector finds objectionable conditions or practices, the FDA can issue a Form 483 (to which the company is expected to respond within 15 business days), which agency officers then review to determine whether there is a regulatory violation and "what further action, if any, is appropriate." *See* FDA, *FDA Form 483 Frequently Asked Questions*, https://bit.ly/30QZc7i (last updated Jan. 9, 2020); FDA, *Investigations Operations Manual 2021* § 5.2.3 (2021), https://bit.ly/3kGY4ev. If the FDA finds a significant violation, it may issue a Warning Letter that "identifies the violation, such as poor manufacturing practices . . . [and] makes clear that the company must correct the problem and provides directions and a timeframe" to do so. FDA, *About Warning and Close-Out Letters*, https://bit.ly/2PLI8cm (last updated Apr. 29, 2019); FDA, *Regulatory Procedures Manual* §§ 4-1-1, 4-1-3 (Feb. 2022), https://bit.ly/3fTls4y. For more serious violations, the FDA may seize adulterated product, 21 U.S.C. § 334(a), withdraw approval, *id.* § 355(e), or refer cases for civil or criminal prosecution, *id.* § 333.

D. FDA's December 2021 Drug Industry Alert Memorandum

The Complaint alleges that plaintiffs became aware of the alleged presence of Benzene in the Products through a petition filed by Valisure LLC, an FDA-registered pharmacy. On November 3, 2021 Valisure filed a citizen's petition with the FDA (the "Valisure Petition") requesting that it issue further guidance with respect to benzene in antiperspirant aerosols pursuant to 21 C.F.R.

§ 10.30. Compl. ¶ 8.[5] Plaintiffs do not allege that defendants had any knowledge of benzene in the Products before the Valisure Petition. In that petition, Valisure requested the FDA to take a number of actions, including "develop guidance documents for the analysis of benzene in body spray products," "review and update the current FDA guidance," and "review and update regulation and published guidance." Valisure Petition at 4–5, 9; Compl. ¶¶ 8–10. Importantly, Valisure also observed that "specifically defined limits of 'poisonous or deleterious' substances, such as benzene, *are not defined* and should be reviewed and addressed by FDA." Valisure Petition at 10 (emphasis added); Compl. ¶¶ 8–10.

On December 23, 2021, the FDA alerted manufacturers to the risk of benzene contamination in certain aerosol drugs.[6] The FDA indicated that it currently "is evaluating the root cause of benzene contamination in certain drugs." In light of its ongoing investigation and "stepwise approach to address the potential for benzene contamination," the FDA recommended that antiperspirants with concentrations of benzene over 2 parts per million ("ppm") should not be distributed but did not require products with benzene below 2 ppm to be recalled. FDA, *FDA alerts drug manufacturers*, *supra* note 6.

ARGUMENT

I. PLAINTIFFS' CLAIMS FAIL FOR LACK OF ARTICLE III STANDING.

Dismissal under Rule 12(b)(1) is appropriate because plaintiffs lack Article III standing. Plaintiffs have not demonstrated that they have "suffered an injury in fact that is concrete, particularized, and actual or imminent." *Transunion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021).

[5] VALISURE, VALISURE CITIZEN PETITION ON BENZENE IN BODY SPRAY PRODUCTS, (Nov. 3, 2021), https://www.valisure.com/wp-content/uploads/Valisure-FDA-Citizen-Petition-on-Body-Spray-v4.0-3.pdf; *see also* Compl. ¶¶ 8–10.

[6] FDA, *FDA alerts drug manufacturers to the risk of benzene contamination in certain drugs*, (last updated May 1, 2015), https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs.

Plaintiffs largely complain that defendants violated the FDCA (they did not). Compl. ¶¶ 3, 20–22, 25–27, 33 (describing alleged violation of FDCA regulations). But the Supreme Court has made clear "an injury in law is not an injury in fact. Only those plaintiffs who have been *concretely harmed* by a defendant's statutory violation may sue that private defendant over that violation in federal court." *Transunion*, 141 S. Ct. at 2205 (emphasis in original).

Plaintiffs fail to plead any such concrete harm. For example, they do *not* allege that they suffered any adverse health consequences from the Products. Compl. ¶¶ 39–45. They likewise do not allege that they will sustain adverse health consequences in the future. *See id.* Remarkably, plaintiffs do *not* allege that they used the Products. *Id.* Instead, plaintiffs allege that because the Products allegedly contained improper amounts of benzene under the FDCA, defendants violated "the basis of the bargain" on which plaintiffs' purchases were based, *id.*; *see also id.* ¶ 36, and therefore the Products were "worthless due to the presence of benzene," *id.* ¶¶ 3, 10, 27, 35, 59, 138, 166; *see also id.* ¶¶ 90, 102 (claiming "the amount of the full purchase price of the Products" was improperly paid). Critically, however, in claiming worthlessness, the Complaint never alleges that the efficacy of the Products was compromised—*i.e.*, that the Products did not function as antiperspirants, which is what plaintiffs bargained for.

Courts repeatedly have dismissed for lack of Article III standing such basis of the bargain theories that a functioning product is worthless due to alleged contamination. *See*, *e.g.*, *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Liab. Litig.*, 903 F.3d 278, 288–89 (3d Cir. 2018) (*J&J Talcum Powder*) (claims that baby powder was unsafe were insufficient to establish injury-in-fact where plaintiff did not allege current or future physical injury); *id.* at 290 ("[A]lthough [plaintiff] characterizes her Baby Powder purchases as economic injuries for which she is entitled to relief, she has failed to allege that the economic benefit she received from that

powder was anything less than the price she paid. In short, she received the benefit of her bargain."); *In re Evenflo Co., Inc. Mktg., Sales Pracs. & Prods. Liab. Litig.*, No. 20-md-02938-DJC, 2022 WL 252331, at *3–5 (D. Mass. Jan. 27, 2022) (dismissing for lack of standing "benefit of the bargain" claims that booster seat was allegedly unsafe for certain children).

This case tracks *J&J Talcum Powder* and others. In *J&J Talcum Powder*, the Third Circuit considered plaintiff's allegations that because talc in the baby power she purchased "could lead to an increased risk of … ovarian cancer," 903 F.3d at 282, the unsafe ingredient rendered the baby powder worthless and thereby deprived her of the benefit of the bargain, *id.* at 287. The Third Circuit swept aside that theory, recognizing that the plaintiff did not allege any personal injury or risk of future personal injury, *id.* at 288–89, that the product failed to function, or "even that the Baby Powder provided her with an economic benefit worth one penny less than what she paid," *id.* at 288; *see also id.* at 289 ("Although [plaintiff] contends that Baby Powder is 'unsafe,' her own allegations require us to conclude that the powder she received was, in fact, *safe as to her*.") (emphasis in original).

The Third Circuit reiterated these principles in *Thorne v. Pep Boys Manny Moe & Jack Inc.*, 980 F.3d 879 (3d Cir. 2020). Like the situation here, plaintiff argued that "she did not receive the benefit of her bargain when she bought tires from Pep Boys that then went unregistered" in violation of federal law. *Id.* at 886. The Third Circuit held that the plaintiff lacked standing because the tires "function[ed] as intended," and plaintiff's claims that the tires violated federal regulatory requirements did not render her "tires worth less at the time of purchase than equivalent registered tires." *Id.* at 887; *see id.* (emphasizing that the Third Circuit will not assign "economic value through mere conjecture").

Similarly, the Ninth Circuit recently dismissed for lack of standing benefit of the bargain-based claims premised on a plaintiff's contention that popcorn allegedly contained ingredients that the FDA had not recognized as safe for use in human food and were instead allegedly capable of causing heart disease and other ailments. *McGee v. S-L Snacks Nat'l*, 982 F.3d 700, 706 (9th Cir. 2020) ("Absent some allegation that [defendant] made false representations about Pop Secret's safety, [plaintiff's] benefit of the bargain theory falls short."). *See also*, *e.g.*, *O'Neil v. Simplicity, Inc.*, 574 F.3d 501, 504 (8th Cir. 2009) (dismissing benefit of the bargain claims for lack of injury where plaintiffs alleged that "they paid for a drop-side crib and now they do not use the crib because the drop-side is not safe"); *Evenflo*, 2022 WL 252331, at *5 (dismissing benefit of the bargain-based injury claims because "all Plaintiffs claim is that the [booster seats], because of these alleged problems, were of no value to them"); *In re Cheerios Mktg. & Sales Pracs. Litig.*, No. 09-cv-2413, 2012 WL 3952069, at *12 (D.N.J. Sept. 10, 2012) (rejecting standing and holding that plaintiffs' allegation of "an apparent and somewhat arcane alleged violation of FDA . . . regulations" did not constitute injury-in-fact) (cleaned up).

Tacitly recognizing these deficiencies (but ignoring the authorities), the Complaint preemptively cites two exceptional cases in which allegations about plaintiffs being deprived the benefit of their bargain have been held sufficient for standing. *See* Compl. ¶¶ 3, 35 (citing *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019); *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, 2021 WL 222776, at *16 (D.N.J. Jan. 22, 2021)). Neither case saves the Complaint from dismissal.

In *Debernardis*, the Eleventh Circuit found standing in a decision expressly "limited to the specific facts alleged in this case—that the plaintiffs purchased dietary supplements that Congress, through the FDCA and [another federal statute], had *banned from sale*." 942 F.3d at 1088

(emphasis added); *accord id.* at 1085 (similar); *id.* at 1086 (similar). Nothing of the sort is alleged here; plaintiffs (at best) assert adulteration, but far from banning products containing benzene, the FDA has permitted their use. *See* Compl. ¶ 10; *see also Marrache v. Bacardi U.S.A., Inc.*, 17 F.4th 1084, 1101 (11th Cir. 2021) ("declin[ing] to extend *Debarnardis*'s limited holding," and explaining that even a situation where the sale of a product illegal under state law but permitted to be sold under federal law is "not valueless"); *Debarnardis*, 942 F.3d at 1088 n.8 (acknowledging that its decision did not speak to the situation where plaintiff "purchased a product that lawfully could be sold") (citing *J&J Talcum Powder* and *O'Neill*).

In *Valsartan*, a judge in the District of New Jersey found that the plaintiffs' injury theory, "[a]lthough somewhat opaque," was sufficient. 2021 WL 100204, at *2. After claiming compliance with the lines the Third Circuit drew in *J&J Talcum Powder* and its progeny, the district court appeared to endorse the idea that standing existed because, as in *Debarnardis*, the drug in question could not be sold because it contained upwards of 150 times the legal limit of certain carcinogens. 2021 WL 100204, at *2, *8; *see also id.* at *9 (drugs were, *inter alia*, "illegal to sell").[7] Again, here, the FDA has not banned the sale of the Products and plaintiffs do not allege any comparable violation of a legal limit for benzene (or a legal limit at all).

Finally, if any claims survive, plaintiffs' requests for injunctive relief must be dismissed for lack of Article III standing. (Counts V–VIII, XI). The Complaint requests injunctive relief regarding defendants' labeling practices. *See, e.g.*, Compl. ¶¶ 116, 126, 137, 153, 183. Even if any plaintiff stated a claim, these requests for injunctive relief must be dismissed for lack of Article III

[7] Even if *Valsartan* were (i) read as broadly as plaintiffs suggest to mean that any contaminant in a product means that a consumer has standing, *see* Compl. ¶ 3 (mere "presence of benzene"), and (ii) any such holding were deemed consistent with *J&J Talcum Powder* and *Thorne* (which it is not), it should be viewed as *dicta* insofar as the district court independently held that plaintiff had established injury-in-fact by alleging "direct economic loss," namely plaintiffs "paid to replace the recalled [drugs] with substitute drugs." 2021 WL 100204, at *8; *see id.* at *10.

standing under Rule 12(b)(1). The Second Circuit has made clear that "to maintain an action for injunctive relief, a plaintiff 'cannot rely on past injury . . . but must show a likelihood that he . . . will be injured in the future.'" *Berni v. Barilla S.p.A.*, 964 F.3d 141, 147 (2d Cir. 2020); *see id.* (explaining that any such future harm must be "imminent"). Plaintiffs plead no possibility of future harm, let alone imminent future harm. *See id.* at 147 ("For several reasons, past purchasers of a product . . . are not likely to encounter future harm of the kind that makes injunctive relief appropriate. In the first place, past purchasers are not bound to purchase a product again—meaning that once they become aware they have been deceived, that will often be the last time they will buy that item."); Compl. ¶¶ 39–44 (alleging that had they known the truth about the Products, they "would not have purchased [them]").

II. PLAINTIFFS' CLAIMS ARE PREEMPTED BECAUSE THEY SEEK TO IMPOSE REQUIREMENTS DIFFERENT FROM OR IN ADDITION TO THE FDCA AND SHOULD BE DISMISSED.

Plaintiffs' claims are expressly preempted because they seek to impose requirements different from or in addition to federal labeling and manufacturing requirements. The Second Circuit recently held in *Critcher v. L'Oreal USA, Inc.*, 959 F. 3d 31 (2d Cir. 2020), that virtually identical claims were pre-empted by the FDCA. *Id*. at 37–38 (FDCA preempted plaintiffs' attempted use of "state laws [to] enforce … FDCA requirements … that labels not be 'false and misleading in any particular'").

Congress has prohibited states from establishing any requirement relating to the regulation of a nonprescription drug "different from or in addition to, or that is otherwise not identical with" a requirement under the FDCA. 21 U.S.C. § 379r(a)(2); *accord Critcher*, 959 F.3d at 35 (recognizing Congress added "an expansive preemption provision" "to ensure that these various

federal requirements are not obstructed by state law").[8] The phrase "not identical to" means "that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food [that] . . . [a]re not imposed by or contained in the applicable [federal regulation] . . . or [d]iffer from those specifically imposed by or contained in the applicable [federal regulation]." 21 C.F.R. § 100.1(c)(4). As the Second Circuit explained, the FDCA preempts both state laws that conflict with the FDCA *and* state laws that provide "requirements that are not *exactly the same* as those set forth in the FDCA and its regulations (*i.e.*, any law that is 'in addition to' the FDCA)." *Critcher*, 959 F.3d at 35–36 (emphasis in original).

Plaintiffs' claims are all premised on allegations that (1) the inactive ingredients should have been disclosed above and beyond the FDCA's requirements; and (2) the Products should have been manufactured using a different process than the FDA-approved CGMPs. Compl. ¶¶ 2, 4 11, 20, 26, 29. Thus, "[i]f Plaintiffs were permitted to move forward with their claims, they would be using state law to impose labeling requirements on top of those already mandated in the FDCA and the regulations promulgated thereunder." *Critcher*, 959 F.3d at 36 ("These would be requirements 'different from' or 'in addition to'—or otherwise 'not identical with'—those requirements that federal law already imposes."). This is "exactly what the FDCA does not permit." *Id.*; *see also Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 376 (S.D.N.Y. 2014) (same). Therefore, plaintiffs' claims are expressly preempted and should be dismissed.

[8] *Critcher* applied the FDCA's preemption provision for cosmetic products. That provision is substantively identical to the neighboring preemption provision for OTC drugs with one notable exception: the drug preemption provision is broader. While the cosmetics provision limits the ban to requirements for "labeling or packaging," the drug preemption provision prohibits the imposition through state law of *any* requirements—whether they relate to labeling, packaging, or any other element of the product at issue. *See Bimont v. Unilever U.S., Inc.*, No. 14-CV-7749 (JPO), 2015 WL 5256988, at * 2 (S.D.N.Y. Sept. 9, 2015) (discussing the "[s]imilar language" of the two preemption provisions).

A. Defendants' Labels Comply With The FDA's Antiperspirant Monograph, And Plaintiffs' Attempt To Impose Additional Benzene-Related Requirements Is Preempted.

Plaintiffs do not (and cannot) allege that the Products fail to comply with any requirement in the 2020 Monograph. The Products' active ingredient—Aluminum Chlorohydrate—is included on the 2020 Monograph's list of permissible active ingredients and the amount of the active ingredient is within the prescribed limits. 2020 Monograph at 2. The labels accurately identify the Products as antiperspirant deodorants, and provide clear directions and warnings, as prescribed by the 2020 Monograph. *See* Declaration of Eamon P. Joyce ("Joyce Decl.") Exs. 1–3; Compl. ¶¶ 2, 11, 29, 30. Nothing more is required given defendants' compliance with the 2020 Monograph.[9] The FDA thus considers the Products to be safe and marketable. *See* 2020 Monograph at 1.

Ignoring all this, plaintiffs attempt to use state law to impose requirements different from or in addition to what the 2020 Monograph and the FDCA require. *See Critcher*, 959 F.3d at 35–37. Plaintiffs claim that if the Products contain "*any* level of benzene," Compl. ¶ 10, they should be deemed "misbranded" in violation of the FDCA, *Id.* ¶¶ 3, 10, 25, 26, 32. That is not the law.

The mere presence of benzene does not render the Products "misbranded." Under the FDCA, a product is "misbranded" only if the label fails to disclose all of its "active ingredients" and "inactive ingredients." 21 U.S.C. § 353(g)(5)(A)(ii)–(iii). A drug's "active ingredients" and "inactive ingredients," however, consist only of substances that are *intended* to be included in the product. *See* 21 C.F.R. § 201.66(b)(2) & (8) ("active ingredient" and "inactive ingredients" are defined in terms of "components"); 21 C.F.R. § 201.3(3) (defining "component" as "any ingredient *intended* for use in the manufacture of a drug product" (emphasis added)). The Complaint readily concedes that the "Products are not designed to contain benzene." Compl. ¶ 2.

[9] Likewise, the FDA's December 2021 Alert Memorandum neither requires nor suggests that manufacturers update labels to disclose the presence of benzene, if any.

The Court should dismiss all of plaintiffs' state law claims alleging deceptive labeling, because they are preempted under federal law. *See Critcher*, 959 F.3d at 38.

B. Plaintiffs Fail To Allege That Defendants Violate The FDA's Current Good Manufacturing Processes And Impermissibly Attempt To Engraft Additional Requirements Onto The CGMPs.

Although plaintiffs do not bring any manufacturing defect claims under state law, they repeatedly suggest that defendants' alleged violations of the FDA's CGMPs somehow gives rise to a claim under state law. Compl. ¶¶ 85, 100, 145, 151; *see also* 21 U.S.C. § 351(a)(2) (explaining that products can be "adulterated" if the manufacturing processes "are not operated or administered in conformity with current good manufacturing practice"); *see supra* at pp. 6–7 (discussing CGMP regulations). Plaintiffs are wrong for multiple reasons.

First, plaintiffs do not and cannot identify any CGMP regulations that speak to benzene (which, as described below, indicates that they again are trying to impose additional or different requirements under the FDCA). Indeed, the *absence* of CGMPs regarding benzene was one of the grievances in the Valisure Petition, Compl. ¶¶ 8–10, which requested the FDA's Commissioner to develop guidance documents and promulgate rules requiring testing for benzene.[10] Instead, the Complaint recites several general CGMPs before concluding, fact-free, that defendants "routinely disregarded the FDA's cGMPs." Compl. ¶¶ 14–21. Which CGMPs did defendants allegedly violate? Plaintiffs never say.[11]

[10] *See* VALISURE, VALISURE CITIZEN PETITION ON BENZENE IN BODY SPRAY PRODUCTS, (Nov. 3, 2021), https://www.valisure.com/wp-content/uploads/Valisure-FDA-Citizen-Petition-on-Body-Spray-v4.0-3.pdf, at 2–3.

[11] Plaintiffs apparently rely on *res ipsa loquitur* to ask the Court to infer that defendants violated CGMP regulations because benzene was found in some samples of the Products. Compl. ¶ 21 ("If Defendants had not routinely disregarded the FDA's cGMPs … Defendant would have identified the presence of the benzene contaminant almost immediately."). Such a claim cannot survive a 12(b)(6) motion. *See Ashcroft v. Iqbal*, 556 U.S. 662, 663-64 (2009) (holding that "inference alone would not entitle [plaintiff] to relief.").

Courts have repeatedly rejected CGMP claims under similar circumstances. The mere allegation that a product was defective, without more, is insufficient to state a claim that a defendant "failed to comply with the FDA's Current Good Manufacturing Practices." *Weber v. Allergan, Inc.*, 940 F.3d 1106, 1114 (9th Cir. 2019); *see also Gale v. Smith & Nephew, Inc.*, No. 12-cv-3614 VB, 2013 WL 9874422, at *3–4 (S.D.N.Y. Sept. 13, 2013) (finding citations to "generally applicable CGMPs … without alleging specific facts to support [plaintiff's] assertions" to be insufficient); *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588–89 (E.D.N.Y. 2009) (rejecting non-specific allegation that defendant violated CGMPs); *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011) ("This complaint is impermissibly conclusory and vague; it does not . . . tell us how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process.").[12]

Second, if anything, plaintiffs seek to impose different or additional benzene-related manufacturing requirements on top of the FDCA—a strategy the Second Circuit rebuffed in *Critcher*. The FDA has already rejected the view that the presence of trace amounts of benzene renders the Products adulterated. In December 2021, the FDA issued an industry alert stating that manufacturers "should not release any drug product batch that contains benzene at or above 2 ppm," but did not prohibit the sale of products with benzene levels below 2 ppm.[13] In short, the FDA's industry guidance directly contradicts plaintiffs' theory here—that *"any* level of benzene in Defendants' Products is unacceptable." Compl. ¶ 10. As such, the mere presence of benzene in the Products is insufficient to establish that the Products were "adulterated" in violation of CGMP

[12] In each of these cited cases, the plaintiffs attempted to pursue state-law manufacturing defect claims and argued that they could escape preemption by inferring CGMP violations; however, unlike plaintiffs here, the plaintiffs in these cases did not argue that an alleged CGMP violation itself gives rise to state law claims.

[13] FDA, *FDA alerts drug manufacturers to the risk of benzene contamination in certain drugs*, (last updated May 1, 2015), https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs.

requirements. To hold otherwise would add a state-law manufacturing requirement "different from or in addition to, or that is otherwise not identical with" the FDCA. *See* 21 U.S.C. § 379r(a)(2); *see also Pearsall v. Medtronics, Inc.*, 147 F. Supp. 3d 188, 198 (E.D.N.Y. 2015) (to hold a defendant liable "in the absence of a specific requirement in the CGMPs … would impose requirements 'different from, or in addition to' those under federal law") (citation omitted).

Third, plaintiffs' claim that the Products violate CGMPs is impliedly preempted by the FDCA. Under the Supreme Court's holding in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), state-law claims based solely upon violations of the FDCA preempt state law. *Accord Glover v. Bausch & Lomb Inc.*, 6 F.4th 229, 237 (2d Cir. 2021) (holding that a "plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)"); *Verzani v. Costco Wholesale Corp.*, No. 09-cv-2117(CM), 2010 WL 3911499, at *3 (S.D.N.Y. Sept. 28, 2010) (dismissing claims predicated on FDCA violations), *aff'd*, 432 F. App'x 29 (2d Cir. 2011). Here, plaintiffs allege that defendants made "deceptive" or "misleading" misrepresentations because, and only because, the Products were purportedly adulterated and misbranded under the FDCA. Compl. ¶¶ 3, 10, 16, 23, 25, 32.[14] They do not provide any independent basis under New York, California, or Florida law that forbids trace levels of benzene in the Products. These claims are—in truth—attempts to privately enforce the FDCA. They cannot be allowed to stand because they are impliedly preempted.

[14] Plaintiffs' inability to premise consumer deception claims on alleged CGMP violations applies with equal force to basing such claims on alleged noncompliance with the 2020 Monograph. *See Critcher*, 959 F.3d at 36–37 ("Congress or the FDA could have chosen to mandate such additional labeling when they established the comprehensive regulatory regime governing cosmetics, but they did not.").

III. EVEN IF THE FDCA DID NOT PREEMPT THE STATE LAW CAUSES OF ACTION, PLAINTIFFS FAIL TO STATE A CLAIM UNDER STATE LAW.

A. PLAINTIFFS' BREACH OF WARRANTY CLAIMS FAIL (COUNTS I, II).

Plaintiffs' breach of warranty claims cannot survive. The express warranty claims fail because defendants made no warranties whatsoever about benzene, and plaintiffs failed to plead that they relied on any alleged warranties. The implied warranty claims also fail, because plaintiffs and defendants are not in privity (which also dooms the Florida plaintiff's express warranty claim) and the Products are fit for their intended purpose—as antiperspirants.

1. Plaintiffs' Express Warranty Claims Fail Because Defendants Did Not Make An Express Warranty About Benzene, and Plaintiffs Did Not Rely On Any Such Warranty.

Under New York, California, and Florida law, breach of express warranty requires plaintiffs to prove "(1) the existence of a material statement amounting to a warranty, (2) the buyer's reliance on this warranty as a basis for the contract with the immediate seller, (3) breach of the warranty, and (4) injury to the buyer caused by the breach." *Colpitts v. Blue Diamond Growers*, 527 F. Supp. 3d 562, 589 (S.D.N.Y. 2021); *Sanders v. Apple Inc.*, 672 F. Supp. 2d 978, 987 (N.D. Cal. 2009) (same); *Wyse v. Gerard Roof Prods., LLC*, No. 3:19-CV-121-TKW-EMT, 2020 WL 1318348, at *2 (N.D. Fla. Mar. 2, 2020) (same).

First, as detailed *infra* at § III.B.1, the Products did not say *anything* about benzene, let alone warrant something about it. The claims fail as a result. *See Harris v. Pfizer, Inc.*, No. 21-cv-6789 (DLC), 2022 WL 488410, at *7 (S.D.N.Y. Feb. 16, 2022) (dismissing express warranty claim for failure to allege that Pfizer "issued any express warranty that their medication was completely safe or free from" contaminant at issue); *Bohac v. Gen. Mills Inc.*, No. 12-cv-05280-WHO, 2014 WL 1266848, at *9 (N.D. Cal. Mar. 26, 2014) (express warranty claims can succeed only where "a reasonable consumer could plausibly read the[] terms to be specific factual representations").

Plaintiffs' own allegations belie their failure to meet the pleading standard for express warranty claims. They ask this Court to infer an express statement about benzene from the label's active and inactive ingredients lists. *See* Compl. ¶ 66 (defendants "issued written warranties by representing that the Products were antiperspirants and deodorants that contained *only* those active and inactive ingredients listed on the Products' labels.") (emphasis added). Such attempts to infer an express warranty are consistently rejected. Again, Judge Cote's *Harris* decision is instructive.

In *Harris*, the court dismissed an express warranty claim because plaintiffs had "not alleged that Pfizer issued any express warranty that their medication was completely safe or free from [the contaminant at issue]." 2022 WL 488410, at *7. This Court should follow suit.[15]

Second, even if plaintiffs had identified an express warranty about benzene, they failed to plead any reliance on such a warranty. *See supra* at pp. 18–19 n.15; *see also, e.g.*, *Oden v. Bos. Sci. Corp.*, 330 F. Supp. 3d 877, 895 (E.D.N.Y. 2018) (dismissing express warranty claim where plaintiffs alleged reliance on promotional statements but "the Complaint [wa]s devoid of any facts that would permit the inference that Plaintiff actually read these statements and directly relied upon them when making the decision to utilize Defendant's product"); *Sanders*, 672 F. Supp. 2d at 987 (dismissing express warranty claim for failure "to allege reasonable reliance on any specific representations"); *Asghari v. Volkswagen Grp. of Am., Inc.*, 42 F. Supp. 3d 1306, 1335 (C.D. Cal. 2013) (same); *Wyse*, 2020 WL 1318348, at *2 (same).

[15] *See also Sarr v. BEF Foods Inc.*, No. 18-cv-6409(ARR), 2020 WL 729883, at *7 (E.D.N.Y. Feb. 13, 2020) (dismissing express warranty claim because the defendant "did not expressly warrant that the Mashed Potatoes did not contain vegetable oil"); *Twohig v. Shop-Rite Supermarkets, Inc.*, 519 F. Supp. 3d 154, 167 (S.D.N.Y. 2021) (similar); *Becerra v. Dr Pepper/Seven Up, Inc.*, No. 17-cv-05921-WHO, 2018 WL 3995832, at *9 (N.D. Cal. Aug. 21, 2018) (dismissing express warranty claim for failure to allege that the term "diet" warranted that consumers would lose weight), *aff'd*, 945 F.3d 1225 (9th Cir. 2019); *Llado-Carreno v. Guidant Corp.*, No. 09-20971-CIV, 2011 WL 705403, at *4 (S.D. Fla. Feb. 22, 2011) (dismissing express warranty claim for failure to allege "any express written or oral statements").

2. Plaintiffs' Implied Warranty Claims Fail For Lack Of Privity And Because The Products Are Fit For Their Intended Purpose.

Plaintiffs' implied warranty claims under New York, California, and Florida law first fail because plaintiffs lack privity with defendants. *See Abraham v. Volkswagen of Am., Inc.*, 795 F.2d 238, 249 (2d Cir. 1986) (affirming dismissal of implied warranty claims under New York and other states' laws for lack of privity); *Clemens v. DaimlerChrysler Corp.*, 534 F.3d 1017, 1024 (9th Cir. 2008) (affirming dismissal of California implied warranty claim due to a "lack of vertical privity"); *see also David v. Am. Suzuki Motor Corp.*, 629 F. Supp. 2d 1309, 1321–22 (N.D. Fla. 2009) (dismissing implied warranty claim for lack of privity). Because each plaintiff purchased their Products from third-party retailers (*i.e.* Rite Aid, Dollar General, Walmart, and Amazon), they lack privity of contract with defendants. *See* Compl. ¶¶ 39–44. As a result, all plaintiffs' breach of implied warranty claims[16] should be dismissed.

Second, to state a claim for a breach of implied warranty of merchantability plaintiffs must allege that the Products were "unfit for the ordinary purposes for which such goods are used." *Twohig*, 519 F. Supp. 3d at 167 (New York law); *see Viggiano v. Hansen Nat. Corp.*, 944 F. Supp. 2d 877, 895–96 (C.D. Cal. 2013) (California law); *Llado-Carreno*, 2011 WL 705403, at *4 (Florida law). Plaintiffs fail to allege the Products are not fit for the precise purpose for which they were intended—as effective *antiperspirants*. *See, e.g.*, Compl. ¶¶ 20, 36. In *Harris*, the district court once again rejected plaintiffs' allegation that a drug was unmerchantable for failure to show how the presence of contaminants "in excess of the legal limit" rendered it "unfit for its ordinary

[16] Privity is also a requirement of an express warranty claim arising under Florida law. *See Mazzeo v. Nature's Bounty, Inc.*, No. 14-60580-CIV, 2014 WL 5846735, *2 (S.D. Fla. Nov. 12, 2014) (dismissing breach of express warranty claim with prejudice for lack of privity because plaintiff bought the contested product from a third-party retailer); *Kaufman v. Pfizer Pharms., Inc.*, No. 1:02-CV-22692, 2010 WL 9438673, at *6–7 (S.D. Fla. Nov. 23, 2010) (same).

purpose." 2022 WL 488410, at *8. Here, too, plaintiffs have not alleged that any amount of benzene affects the Products' intended use as antiperspirants.

B. Plaintiffs' Statutory State Law Claims Fail Because The Complaint Does Not Allege A Misrepresentation Or Plead All Required Elements For A Misrepresentation By Omission (Counts III–IX).

Each of plaintiffs' statutory consumer claims should be dismissed because, although plaintiffs generically complain of misrepresentations, they fail to identify a single affirmative misleading or deceptive statement. Plaintiffs also fail to allege any actionable omissions theory because they have not plausibly alleged that defendants knew the Products may contain benzene before plaintiffs purchased the Products—and defendants' knowledge is necessary to establish an omissions claim under each statutory consumer claim.[17]

1. Plaintiffs Fail To Allege A Misrepresentation.

Plaintiffs generically claim that defendants "misrepresent[ed] that the Products (i) would not contain dangerously high levels of benzene, and (ii) are generally recognized as safe for human use." Compl. ¶ 85. But plaintiffs do not and cannot identify any statement on the Products' labels (or by defendants anywhere else) regarding benzene or safety for human use. *See* Joyce Decl., Exs. 1–3 (labels themselves). Courts repeatedly have recognized—including Judge Cote just weeks ago—that the presence of a contaminant not listed on a drug's label is not a misrepresentation.

[17] Even if an affirmative statement or actionable omission existed, this court should still dismiss statutory claims brought by the California plaintiffs under the UCL, CLRA, and FAL. Under those statutes, a plaintiff must allege sufficient facts to show that they actually relied on the particular statements that they are challenging. *See Reid v. Johnson & Johnson*, 780 F.3d 952, 958 (9th Cir. 2015). To meet this burden, plaintiffs must plead that the misrepresentation was "material" to them, i.e., "that without the misrepresentation, plaintiff[s] would not have acted as [they] did." *Cattie v. Wal-Mart Stores, Inc.*, 504 F. Supp. 2d 939, 946 (S.D. Cal. 2007) (citing *Caro v. Procter & Gamble Co.*, 18 Cal. App. 4th 644, 668 (1993)). Plaintiffs have not met that standard. They simply make a conclusory claim that they "relied on these representations and warranties" when purchasing the Products. Compl. ¶¶ 42, 43. The only more detailed allegation is simply implausible. Plaintiffs allege that "no reasonable consumer would have paid any amount for products containing benzene, a known carcinogen and reproductive toxin, much less above the limits set by the FDA." *Id.* ¶ 33. But common sense dictates otherwise. Consumers purchase a myriad of products that contain benzene (an obvious example being gasoline) and products that are carcinogenic (an obvious example being alcoholic beverages). Without a plausible allegation of reliance, this Court must dismiss the California plaintiffs' UCL, CLRA, and FAL claims. *See Iqbal*, 556 U.S. at 663–64.

Harris, 2022 WL 488410, at *7 (absent an express statement to the contrary, "[i]t is not enough to allege that the plaintiffs inferred from this label that the product did not contain" contaminants); *see*, *e.g.*, *Zottola v. Eisai Inc.*, 20-cv-02600 (PMH), 2021 WL 4460563, at *5 (S.D.N.Y. Sept. 29, 2021) (dismissing GBL claims because plaintiff "only refer[red] to unspecified misleading representations contained in the Medications' 'labels and disclosures'" regarding safety "as opposed to challenging a particular representation"); *Womack v. Evol. Nutrition Assocs.*, No. 6:21-cv-00332, 2021 WL 5906340, at *10 n.8 (N.D.N.Y. Dec. 14, 2021) (similar).

2. Plaintiffs Fail to Allege That Defendants Knew The Products Contained Benzene Before Plaintiffs Purchased The Products.

Plaintiffs' omissions theory—that the *absence* of a warning about benzene constitutes deception and falsity under state law—also fails as a matter of law. Compl. ¶¶ 85, 100, 113, 125, 131, 147. Under the laws of New York, California, and Florida, plaintiffs must plausibly allege that defendants had *knowledge* of relevant facts that they allegedly withheld. Plaintiffs have not—and cannot—do so.

Again, just weeks ago, Judge Cote dismissed an indistinguishable GBL claim predicated on an omissions theory because the plaintiffs did not plead that the manufacturer "knew about any . . . contamination in the medication that the plaintiffs purchased at the time they purchased it." *Harris*, 2022 WL 488410, at *7 (noting that plaintiff did "not plausibly allege that Pfizer knew about the nitrosamine contamination before it issued its recall"); *accord Morales v. Kimberly-Clark Corp.*, No. 18-cv-7401 (NSR), 2020 WL 2766050, at *5 (S.D.N.Y. May 27, 2020) (dismissing claims because "[a] defendant's failure to reveal facts of which even it was unaware will not lead to liability under G.B.L. § 349"); *In re Sling Media Slingbox Advert. Litig.*, 202 F. Supp. 3d 352, 359 (S.D.N.Y. 2016) (same, "[t]he key, of course, is that the defendant 'possess' the information that the plaintiff claims it improperly withheld."); *see*, *e.g.*, *Wilson v. Hewlett-*

Packard Co., 668 F.3d 1136, 1145 (9th Cir. 2012) ("[U]nder the CLRA, plaintiffs must sufficiently allege that a defendant was aware of a defect at the time of sale to survive a motion to dismiss."); *Soo v. Lorex Corp.*, No. 20-CV-01437-JSC, 2020 WL 5408117, at *8 n.6 (N.D. Cal. Sept. 9, 2020) (dismissing UCL and FAL claims because plaintiffs failed to show that "Defendants knew a functionality issue existed at the time they sold" the products); *Matthews v. Am. Honda Motor Co.*, No. 12-60630, 2012 WL 2520675, at *3 (S.D. Fla. June 6, 2012) ("Florida courts have recognized that a [Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA")] claim is stated where the defendant *knowingly* fails to disclose ….") (emphasis added) (citation omitted).

As in *Harris*, plaintiffs fail to plead any facts that defendants knew the Products contained benzene before their purchases, the most recent of which was in September 2021. Compl. ¶¶ 39, 44. Indeed, plaintiffs allege that defendants "knowingly, *or at least negligently*" introduced Products "containing dangerous amounts of benzene." *Id*. ¶ 23. Aside from being conclusory, plaintiffs' allegation as to purported negligence is a telling concession—negligence simply is not knowledge. The first factual allegation that approaches knowledge is the publication of the Valisure Petition in November 2021, which post-dates all of plaintiffs' alleged purchases.[18]

Moreover, as to claims against TCP, plaintiffs bring omission claims for purchases occurring before June 2021. *Id*. ¶¶ 40, 42. Plaintiffs ignore the fact that TCP acquired the Products from Idelle in June 2021.[19] Logically, TCP could have no knowledge of or obligation to disclose potential contaminants for a Product it does not own or distribute.

[18] Moreover, even if the petition had predated those purchases, it would be a legally insufficient basis for proceeding on an omissions theory because it is not information known to defendant alone. *See*, *e.g.*, *Oswego Laborers' v. Marine Midland Bank*, 85 N.Y.2d 20, 26 (1995); *Dimond v. Darden Rests., Inc*., No. 13-cv-5244 KPF, 2014 WL 3377105, at *14 (S.D.N.Y. July 9, 2014) (dismissing GBL claim for failure to allege the plaintiff could not "reasonably obtain" the same information as defendant). Further, the complaint does not plausibly allege that defendants were aware of the Valisure Petition in November 2021.

[19] https://www.globenewswire.com/news-release/2021/06/08/2243993/0/en/HRB-Brands-Announces-Acquisition-of-Personal-Care-Brands-from-Helen-of-Troy.html

3. Plaintiffs Fail To Plead Their Claims With Sufficient Particularity.

Plaintiffs fail to plead their fraud-based claims (Counts V through X) with the specificity required under Rule 9(b). *See* Fed. R. Civ. P. 9(b); *See Leon v. Cont'l AG*, 301 F. Supp. 3d 1203, 1226 (S.D. Fla. 2017) (applying Rule 9(b) to a FDUTPA claim sounding in fraud); *In re Sony Gaming Networks & Customer Data Sec. Breach Litig.*, 903 F. Supp. 2d 942, 967 n.20 (S.D. Cal. 2012) ("Rule 9(b)'s heightened pleading standards apply equally to claims for violation of the UCL, FAL, or CLRA that are grounded in fraud.") (citing *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009)); *Innovative Custom Brands, Inc. v. Minor*, No. 15-cv-2955 (AJN), 2016 WL 308805, at *4 (S.D.N.Y. Jan. 25, 2016) ("If an unjust enrichment claim is premised on fraudulent conduct, it is subject to Rule 9(b)'s particularity requirement.") (citation omitted).[20]

Plaintiffs fail to plead with sufficient particularity. With the exception of Ms. Molina, plaintiffs allege that they each purchased "a canister" and relied on defendants' labels and representations; but plaintiffs fail to allege what exactly they reviewed or which statements were false or misleading. As such, the Court should dismiss plaintiffs' fraud-based claims. *See, e.g.*, *Miller v. HSBC Bank U.S.A., N.A.*, No. 13-cv- 7500(RWS), 2015 WL 585589, at *7 (S.D.N.Y. Feb. 11, 2015) (dismissing claim for failure to plead "the who, what, when, where and how of the alleged fraud") (citation omitted); *Zottola*, 2021 WL 4460563, at *9 (dismissing fraud claim based only on "conclusory" allegations defendant "knew" of and "concealed the allegedly defective nature of Medications").

[20] *See also W.W. Sports Importadora Exportadora E Comercial LTDA v. BPI Sports, LLC*, No. 16-cv-60147(WPD), 2016 WL 9375202, *4–5 (S.D. Fla. Aug. 11, 2016) (applying Rule 9(b) to unjust enrichment claim under Florida law); *In re Arris Cable Modem Consumer Litig.*, No. 17-CV-01834-LHK, 2018 WL 288085, at *10 (N.D. Cal. Jan. 4, 2018) (same under California law).

C. New York Plaintiffs Fail To State A Claim Under The GBL (Counts III, IV).

The New York plaintiffs' GBL claims should be dismissed for two reasons: first, GBL claims may not be based on alleged FDCA violations under *Conboy v. AT&T Corp.*, 241 F.3d 242, 257–58 (2d Cir. 2001), and its progeny; and second, the plaintiffs did not suffer a cognizable injury under New York law.

1. Second Circuit Law Precludes Plaintiffs From Predicating Deception On The Alleged Violation Of Another Statute.

Each of plaintiffs' claims is premised on allegations that the Products' labeling statements are false and misleading because they are "misbranded" and "adulterated" under the FDCA. Compl. ¶¶ 3, 10, 25, 26, 32. But alleged violations of the FDCA cannot serve as the sole predicate for deceptive behavior. The alleged violation of another statute, especially one lacking a private right of action, is insufficient to state a claim under GBL § 349 claim. *Conboy v. AT&T Corp.*, 241 F.3d at 257–58 (rejecting plaintiff's attempt to effectively create a private right of action under a state statute by arguing that defendant "engaged in a 'deceptive act' within the meaning of [GBL] Section 349 by violating [the other state law]"); *see Broder v. Cablevision Sys. Corp.*, 418 F. 3d 187, 199–200 (2d Cir. 2005) (applying *Conboy*, and holding that § 349 cannot be used to "circumvent the lack of a private right of action for violation of a *federal* law," and reiterating that circuit law precludes claiming that deception exists because another statute or regulation was violated, particularly one "that on its face does not address deceptive or misleading behavior").

2. New York Plaintiffs' Fail To Plead A Cognizable Injury.

A claim under the GBL predicated on deception about the health risks of a product fails if the claimed damages are solely for recoupment of the entire purchase price. That is precisely what

plaintiffs here claim. *See, e.g.*, Compl. ¶¶ 3, 10, 27, 35, 39, 41, 85–86, 99, 100.[21] The New York Court of Appeals in *Small v. Lorillard Tobacco Co.* affirmed dismissal of a GBL claim because the plaintiffs "confine[d] the relief sought solely to monetary recoupment of the purchase price of the [products at issue]." 94 N.Y.2d 43, 56 (1999) (Wesley, J.); *see id.* at 51 ("They seek only the reimbursement of the purchase cost of cigarettes that they claim they would not have bought, but for defendants' fraudulent and deceptive practices."). The court held that the cancerous qualities of deceptively marketed cigarettes did not create a cognizable injury based on the claim that plaintiffs were entitled to recoupment of the purchase price. *Id.* at 56. The rule in *Small* has been routinely applied by other courts to bar GBL claims where the damages sought are a full refund of the purchase price. *Servedio v. State Farm Ins. Co.*, 889 F. Supp. 2d 450, 452 (E.D.N.Y. 2012) ("The rationale of *Small* and its progeny is that deceived consumers may nevertheless receive—and retain the benefits of—something of value, even if it is not precisely what they believed they were buying."); *Zottola*, 2021 WL 4460563, at *3 (finding no injury under *Small* where plaintiffs' "alleged injury was purely economic: the purchase price of the Medications."); *see also Himmelstein, McConnell, Gribben, Donoghue & Joseph, LLP v. Matthew Bender & Co.*, 100 N.Y.S.3d 227, 229 (N.Y. App. Div., 1st Dep't 2019) ("The GBL § 349 claim was correctly dismissed because the only injury alleged … is the amount that plaintiffs paid for the book, which does not constitute an injury cognizable under the statute."), *aff'd on other grounds*, 37 N.Y.3d 169 (2021). This Court should follow *Small* and its progeny and dismiss plaintiffs' GBL claims because they have not alleged a cognizable injury under the law.

[21] Whether the New York Plaintiffs pleaded a cognizable injury under the GBL requires a separate inquiry with a higher bar than that of Article III standing. *See Colpitts v. Blue Diamond Growers*, 527 F. Supp. 3d 562, 576 (S.D.N.Y. 2021). The Second Circuit has held that Article III "[i]njury in fact is a low threshold, which . . . need not be capable of sustaining a valid cause of action." *Ross v. Bank of Am.*, 524 F.3d 217, 222 (2d Cir. 2008).

D. Plaintiffs' Unjust Enrichment Claims Fail (Count X).

Plaintiffs' claim for unjust enrichment fails for two independently sufficient reasons: plaintiffs allege they are in a contractual relationship with defendants and plaintiffs' alleged basis for their claim is a purported statutory violation. As described immediately above—there is no contractual privity between the parties.

First, plaintiffs' claim fails because they rest on quasi-contractual principles applicable only in the absence of an express contract governing the subject at issue. *See, e.g.*, *Paracor Fin., Inc. v. Gen. Elec. Cap. Corp.*, 96 F.3d 1151, 1167 (9th Cir. 1996) ("[T]he existence of a valid and enforceable written contract … ordinarily precludes recovery in quasi-contract" under New York and California law) (internal citations omitted); *MacDraw, Inc. v. The CIT Grp. Equip. Fin, Inc.*, 157 F.3d 956, 964 (2d Cir. 1998); *Spears v. SHK Consulting & Dev., Inc.*, 338 F. Supp. 3d 1272, 1278 (M.D. Fla. 2018) (same in Florida). But plaintiffs hold themselves out as "contracting parties" with defendants, *see* Compl. ¶ 157, while bringing breach of warranty claims regarding the ingredients displayed on the Products' labels. *See Id.* ¶¶ 66, 67, 71, 72. Therefore, these quasi-contractual claims fall on plaintiffs' own allegations of an express agreement on the same subject, even though the Products did not warrant specifically about the presence of benzene, *see supra* § III.A.1.

Second, plaintiffs' alleged wrong supporting their unjust enrichment claim is the purported violations of the FDCA, which they in turn seek to enforce through other statutory consumer protection claims and common law causes of action. As set forth above, Plaintiffs have not shown any of the violations on which their unjust enrichment claims rely, and thus there is no unjust conduct alleged. *Supra* §§ II-III.B. But even assuming, *arguendo* that they had, plaintiffs may not support an unjust enrichment claim by porting over the wrong from another cause of action. *AstroTel, Inc. v. Verizon Fla., LLC*, No. 8:11-cv-2224-T-33TBM, 2012 WL 1581596, at *10 (M.D.

Fla. May 4, 2012) ("[a]s soon as a claimant relies on a wrong to supply the unjust factor, the right on which he relies arises from that wrong, not from unjust enrichment."); *see, e.g.*, *Harris*, 2022 WL 488410, at *9 (An unjust enrichment claim "is not available where it simply duplicates, or replaces, a conventional contract or tort claim.") (citing *Corsello v. Verizon N.Y., Inc.*, 18 N.Y.3d 777, 790 (2012)); *In re Sony PS3 Other OS Litig.*, 551 F. App'x 916, 923 (9th Cir. Jan. 6, 2014) (affirming dismissal of unjust enrichment claim because "[i]n light of the adequate legal remedies available, Plaintiffs cannot state a claim for unjust enrichment").[22]

E. Florida Plaintiff Fahey's Medical Monitoring Claim Fails (Count XI).

Plaintiff Fahey fails to state a claim for medical monitoring. Under Florida law, Fahey must demonstrate *each* of the following elements:

> (1) exposure greater than normal background levels; (2) to a proven hazardous substance; (3) caused by the defendant's negligence; (4) as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious latent disease; (5) a monitoring procedure exists that makes the early detection of the disease possible; (6) the prescribed monitoring regime is different from that normally recommended in the absence of the exposure; and (7) the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles.

Petito v. A.H. Robins Co., 750 So. 2d 103, 106–07 (Fla. App. 1999); *accord Perez v. Metabolife Int'l, Inc.*, 218 F.R.D. 262, 270–71 (S.D. Fla. 2003). Fahey fails to plead facts in support of many of those elements. *See, e.g.*, *Coffie v. Fla. Crystals Corp.*, 460 F. Supp. 3d 1297 (S.D. Fla. 2020) (granting motion to dismiss medical monitoring claim for failure to allege sufficient facts to support the *Petito* elements).

[22] California plaintiffs' UCL and FAL claims fail for the same reason. Under California law, remedies available under these statutes are "generally limited to . . . equitable remedies"—making them "'subject to fundamental equitable principles, including inadequacy of the legal remedy.'" *Gardner v. Safeco Ins. Co. of Am.*, No. 14-cv-02024-JCS, 2014 WL 2568895, *7 (N.D. Cal. June 6, 2014) (citations omitted). *See Salas v. Toyota Motor Sales, U.S.A., Inc.*, No. cv-15-8629 FMO (Ex), 2016 WL 7486600, *13 (C.D. Cal. Sept. 27, 2016) (citing cases and dismissing UCL and unjust enrichment claims where plaintiff sought CLRA damages); *see also, e.g.*, *Robinson v. J.M. Smucker Co.*, No. 18-cv-04654-HSG, 2019 WL 2029069, *6 (N.D. Cal. May 8, 2019) (dismissing UCL claim because "an adequate remedy [wa]s available at law in that Plaintiff may seek money damages for a CLRA violation").

To begin, Fahey has not even pled that she actually *used* the product. Compl. ¶ 44. Without that, the Court simply cannot infer that she was exposed to "greater than normal background levels"—or any level—of a "hazardous substance." And even if Fahey had alleged use, she has not shown that *any* amount of benzene, no matter how small, creates a "significantly increased risk of contracting a serious latent disease."

Moreover, Fahey has not shown that the presence of benzene in the Products was caused by defendants' negligence or that defendants were negligent in failing to warn plaintiffs that the Products contained benzene. To show negligence under Florida law, a plaintiff must "prove that a manufacturer or distributor failed to take care and provide warnings that a reasonably careful manufacturer would have known and warned about." *Faddish v. Pumps*, 881 F. Supp. 2d 1361, 1370 (S.D. Fla. 2012); *Crawford v. ITW Food Equip. Grp.*, 977 F.3d 1331, 1358 (11th Cir. 2020). As explained *supra* § II.B, the Complaint fails to allege that a reasonably careful manufacturer or distributor would have known to test for benzene or warn consumers about the potential presence of benzene.[23]

Finally, Fahey failed to allege how her prescribed monitoring regimen is reasonably necessary according to contemporary scientific principles based on the allegedly detected levels of benzene found in defendants' Products. For these reasons, the Court should dismiss Fahey's claim for medical monitoring.

CONCLUSION

For the forgoing reasons, defendants respectfully request that the Court grant their motion to dismiss in its entirety.

[23] The FDA alert memorandum and the Valisure petition, as discussed above, both post-date Fahey's purchases.

Respectfully submitted,

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